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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,553	08/05/2003	Eli Cohen	29452/39269	6039
4743	7590	10/31/2006	EXAMINER	
MARSHALL, GERSTEIN & BORUN LLP 233 S. WACKER DRIVE, SUITE 6300 SEARS TOWER CHICAGO, IL 60606			SHEN, BIN	
			ART UNIT	PAPER NUMBER
			1657	

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/634,553

Applicant(s)

COHEN ET AL.

Examiner

Bin Shen

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 and 23-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u> </u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The IDS received 8/5/2003, 8/25/2003, 5/7/2004, 9/13/2004, 10/18/2004, 1/25/2005 have been entered.

Election

Applicant's election with traverse of Group II, claims 12-22, in the reply filed on 8/14/2006 is acknowledged. The traversal is on the ground(s) that the Groups are not patentably distinct and there is no search burden. This is not found persuasive for the reasons of record in the restriction requirement. There is also search burden in the non-patent literature, thus the restriction is proper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-11, 23-27 are nonelected and thus are withdrawn from further consideration.

Claims 12-22 are presented for examination on the merits.

Claim Objections

1. Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 15 recites the second blood sample comprises a blood sample prepared without heparin which is inconsistent with/opposite to claim 12 that recites a second blood sample characteristic in the absence of substantial platelet activation which requires more heparin.

Art Unit: 1657

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 12-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is rendered vague and indefinite by the phrase "in the absence of substantial platelet activation" (read as with more heparin that inhibits platelet activation) because it is inconsistent with claim 15 which require the second blood sample comprises a blood sample prepared without heparin.

3. The term "substantially completely" in claims 16 and 17 is a relative term, which renders the claim indefinite. The term "substantially completely" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. "substantially" and "completely" define two different scopes, which are not the same. Clarification is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1657

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 12-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen (WO01/96879A2), in view of Pravinkumar et al. (British J of Anaesthesia 2003;90(5)676-685).

Cohen teaches an apparatus for monitoring heparin (abstract and page 9, line 5) comprising: means for testing a first blood sample a first blood sample characteristic in the presence of heparin; means for testing a second blood sample a second blood sample characteristic in the absence of heparin (page 10, lines 3-5); means for comparing the first and second blood sample characteristic to determine the effects of heparin, wherein the first blood sample characteristic comprises at least one of a clot strength measurement, a clot elasticity measurement, a clot rate of formation measurement, a clot time to formation measurement a clot rate of lysis measurement of the first blood sample and the second blood sample characteristic comprises at least one of a clot strength measurement, a clot elasticity measurement, a clot rate of formation measurement, a clot time to formation measurement a clot rate of lysis measurement of the second blood sample (page 7, lines 1-2, page 8, 2nd and 3rd full paragraph and page 9, 2nd paragraph), wherein the second blood sample characteristic represents a fibrin contribution to hemostasis (page 7, line 1, and page 11, 1st full paragraph), wherein the second blood sample comprises a blood sample without heparin (page 10, line 4), wherein the first blood sample

Art Unit: 1657

comprises a first heparinized blood sample prepared with a first quantity of heparin and a second blood sample comprises a second heparinized blood sample prepared with a second quantity of heparin, different than the first quantity of heparin (page 10, lines 3-5), wherein each of the first blood sample and the second blood sample comprises a platelet rich plasma-patient plasma mixture, wherein each of the first blood sample and the second blood sample comprises patient whole blood (page 7, lines 20-22, and page 1, lines 14-16), wherein each of the first blood sample and second blood sample comprises an activator (page 11, 1st full paragraph). In the presence of heparin, the first blood sample characteristic will (inherently) represents a contribution to hemostasis of activated platelets in the presence of HiT II because heparin can induce HiT II (see Pravinkumar below).

Cohen does not teach determining heparin-induced thrombocytopenia II complex, the second blood sample comprises a blood sample prepared with a quantity of heparin sufficient to substantially completely suppress platelet activation.

Pravinkumar teaches that heparin induces thrombocytopenia II which form a white clot (page 676, right column, 1st full paragraph and page 677, lines 20-23), and suggest that the induction is dose responsive (page 680, 1st full paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the apparatus of Cohen to determine heparin-induced thrombocytopenia II complex (HiT II) because Pravinkumar teaches that heparin induces thrombocytopenia II (see above). One would have been motivated to make the modification because Cohen et al. specifically described the use of the apparatus to monitor heparin therapy

Art Unit: 1657

and Pravinkumar et al. teach that heparin induces thrombocytopenia II and it is imperative to discontinue all source of heparin before the laboratory confirmation of HiT (page 683, beginning of Summary), and would reasonably have expected success in view of Pravinkumar's teaching that heparin induces thrombocytopenia II in a dose responsive manner, wherein the second blood sample can be prepared with a quantity of heparin sufficient to substantially completely suppress platelet activation.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

5. No claim is allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status

Art Unit: 1657

of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, Ph.D., whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her

Art Unit: 1657

office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571) 272-0925.



MICHAEL MELLER
PRIMARY EXAMINER

B Shen

Art Unit 1657